

tion (6-month ER visits and hospitalizations). Comparisons in each of these health-related topics were made between respondents with IBS-C versus non-FGID, asthma, migraine, and RA. Comparisons controlled for age and gender. **RESULTS:** Prevalence of IBS-C was 0.67%, 1.03%, and 0.91% in the US, UK, and France, respectively. Most respondents were female (>65%) and mean age ranged from 47.7 to 49.8 years. In each country, mean SF-12 physical (PCS) and mental (MCS) summary scores were statistically ($p < 0.001$) and clinically meaningfully (≥ 2.5) lower than the non-FGID group. With few exceptions, PCS and MCS scores of IBS-C were significantly ($p < 0.05$) lower than scores for asthma, migraine, and RA. In each country, IBS-C reported significantly ($p < 0.001$) greater absenteeism and worse presenteeism and greater overall work productivity loss and daily activity impairment than non-FGID, and with few exceptions, worse than asthma, migraine, and RA. Lastly, in each country the number of ER and hospital visits was significantly higher ($p < 0.01$) for IBS-C compared to non-FGID and, with few exceptions, higher than asthma, migraine, and RA. **CONCLUSIONS:** In the three countries respondents with IBS-C showed significant and clinically meaningful deficits in HRQoL and work productivity and elevated health care utilization compared with other chronic conditions.

PGI53

ASSESSMENT OF SERIAL TRANSVERSE ENTEROPLASTY: SYSTEMATIC REVIEW
Yoo KI

NECA, Seoul, South Korea

OBJECTIVES: The purpose of this study was to evaluate the safety and effectiveness of serial transverse enteroplasty (STEP). **METHODS:** The clinical utility of STEP was first reviewed in three textbooks and secondly the safety and the effectiveness of the STEP were assessed based on a systematic review. 575 articles were searched using database (KoreaMed, Ovid-MEDLINE, Ovid-EMBASE and Cochrane Library, etc.) and eliminated according to inclusion/exclusion criteria, duplicate search results. Finally, 9 articles (2 cohort study and 7 case studies) were used. Two evaluators performed independently throughout each process. The article's quality evaluated by the SIGN's tool and the grade of recommendation were selected. **RESULTS:** A review of the textbooks revealed that STEP is conducted on patients with refractory SBS. And the advantages of STEP are that it is technically straightforward, can form a uniform bowel channel regardless of variable underlying bowel dilation, and can be repeated if the bowel subsequently radiated. The safety of STEP was assessed based on procedure-related complications in 6 articles. The complication rate of STEP was overall 6.3–25%, bleeding 6.3–12.5%, obstruction 6.3–22%, anastomosis leak 2.3–16.7% and stricture 11–20%. The complication rate of the STEP versus the Bianchi LILT was no significantly difference. The effectiveness of STEP was assessed based on the enteral autonomy and survival rate in 9 articles. There was a trend toward a decreased rate of PN after STEP. As a result, the 33–56% patients who underwent STEP were weaned off within one year and 83–88% after one year. Survival was 83% with maximum follow-up of 68 months. **CONCLUSIONS:** The safety of STEP was at an acceptable level as complications reported in studies generally occur after an intestinal operations and such problems can be corrected surgically. The clinical utility of STEP was described in the textbooks as a non-transplantation procedure and all the selected articles was reported on wean-off parenteral nutrition. Therefore, there is evidence for the safety and effectiveness of STEP performed on patients with refractory short bowel syndrome for promoting enteral nutrition (Recommendation grade C).

PGI54

PRESCRIBING PATTERN OF DRUGS FOR ULCERATIVE COLITIS IN JAPAN

Tomita N¹, Kanatani Y¹, Nakagawa Y²¹National Institute of Public Health, Saitama, Japan, ²National Hospital Organization Shikoku

Medical Center for Children and Adults, Zentjuji city, Japan

OBJECTIVES: Ulcerative colitis is one of 56 designated diseases for the Specified Disease Treatment Research Program that provides co-payment reduction or exemption according to disease severity and patients' income levels. Under the fee-for-service payment system, such financial assistance program may influence drug utilisation. The objective of this study is to assess the overall drug prescribing pattern for ulcerative colitis. **METHODS:** Claims data with indication for ulcerative colitis were extracted from the Social Health Insurance claims data processed from December 2009 to February 2010 and from February to April 2011. Extracted data were analysed and compared in terms of patients' age, types of public subsidy, prescribed places (clinic/hospital or pharmacy) and pharmacologic classes. **RESULTS:** Total numbers of patients were 67,480 for the former duration and 84,450 for the latter duration. Among them, patients who were entitled to the Specified Disease Treatment Research Programme were 47,103 and 60,231 respectively. The most commonly used drug was mesalazine which accounted for 56% and 59%. Infliximab was prescribed mainly for those entitled to the Specified Disease Treatment Research Program. Of total infliximab dose, 23 % and 30% were with steroid and 33% and 38% were with mesalazine. Generic utilisation rate for patients entitled to the Specified Disease Treatment Research Programme or other financial assistance programs was low. **CONCLUSIONS:** The highest utilization of infliximab and low generic utilization were observed for patients entitled to the Specified Disease Treatment Research Programme. Prescribing pattern of drugs suggested that some cases did not follow clinical guidelines. Adherence to clinical guideline recommendations should be promoted.

PGI55

PATIENTS DIAGNOSTIC THERAPEUTIC PATHWAYS FOR HCV PATIENTS IN ITALY: IMPACT OF REGIONALIZATION IN TREATMENTS AND GUIDELINES

Lanati EP¹, Lidonnici D¹, Gasbarrini A², Ruggeri M³, Sacchini D³, Caporaso N⁴, Fagioli S⁵¹MA Provider, Milano, Italy, ²Poliniclinico Gemelli, Rome, Italy, ³Università Cattolica del Sacro Cuore, Rome, Italy, ⁴Università di Napoli Federico II, Napoli, Italy, ⁵Papa Giovanni XXIII Hospital, Bergamo, Italy

OBJECTIVES: The aim of this study is to describe the differences in Patients Diagnostic Therapeutic Pathways (PDTA) among Italian Regions, as the Italian scenario shows substantial differences in terms of Regional guidelines, organization and allocated budget. **METHODS:** The Regional policies were examined analyzing

the PDTAs of the most representative Regions. The analysis investigates the following Regional characteristics: establishment of a working group to define the PDTA, the gap of criteria for prescribing centers with the AISF guidelines, indication of therapeutic scheme for the different kind of patients, budget allocation, characteristics of the management model and existence of a follow up system. **RESULTS:** The results of the study show that, besides some common characteristics observed in all Regions (e.g. the presence of working group and criteria for the eligibility of patients and identification of prescribing centers), there is a substantial heterogeneity in Regional guidelines, especially regarding budget allocation, management model and follow up system. Indeed, if in some Regions like Basilicata and Veneto there is a specific budget allocation (respectively €1,2 ml and €12 ml in 2014), the management model is based on Hub and Spoke system and the follow up mechanism is clearly set up, in other Regions like Lombardy and Liguria the guidelines are more vague, detailing only few criteria. These Regional differences are confirmed by other two data: the timespan between the market authorization of the Triple Therapy for HCV patients and the integration in Regional guidelines (e.g. 17 days in Veneto and 147 days in Emilia Romagna) and the number of prescribing centers per million inhabitants (6,92 in Basilicata and 1,85 in Veneto). **CONCLUSIONS:** The study demonstrate that, with a view to the future novel drugs, a common disease management model, including common guidelines and organizational model, is essential to avoid regional disparities in HCV therapies access.

PGI56

CLAIMS DATABASE ANALYSIS OF PATIENTS WITH CHRONIC HEPATITIS C IN JAPAN

Murata T, Hanada K, Shibahara H

CRECON Research & Consulting Inc., Tokyo, Japan

OBJECTIVES: This retrospective study aimed to evaluate the actual chronic hepatitis C (CHC) treatment in Japan including interferon (IFN) treatment using Japanese claims data provided by Japan Medical Data Center Co., Ltd (JMDC). **METHODS:** All claims data for 9,634 patients having a history of diagnosis related to CHC, liver cirrhosis (LC), or hepatocellular carcinoma (HCC) among Japanese claims data from January 2005 to October 2013 provided by JMDC were analyzed in this study. Treatment patterns and costs were evaluated in CHC patients newly diagnosed during the study period. **RESULTS:** 3,546 newly diagnosed CHC patients were included in this analysis. The median follow-up period was 21.0 months. The CHC treatment including IFN was not implemented in most cases (76.8%) during the follow-up period. The rate of IFN treatment was 7.0%. The combination therapy of IFN and ribavirin (RBV) was the most frequently used in IFN treatment. Median period of first line treatment to the discontinuation was 7.0 months in patients with IFN + RBV. The mean annual total cost in CHC patients with IFN, CHC patients without IFN with other drugs (e.g. ursodeoxycholic acid), CLC patients were 3.5 million yen (\$35,000), 2.0 million yen (\$20,000), 3.1 million yen (\$31,000), respectively. The mean annual number of outpatient visits in patients with IFN + RBV, patients without IFN with other drugs were 56.7 and 37.5 visits, respectively. **CONCLUSIONS:** The CHC treatment including IFN was not implemented in most cases despite having the CHC diagnosis. Furthermore, IFN treatment completion rate are low. One of the main causes of these facts would be adverse effects associated with IFN treatment. New drugs with fewer adverse effects are awaited for the future.

MUSCULAR-SKELETAL DISORDERS – Clinical Outcomes Studies

PMS1

IMPACT OF APREMILAST ON PHYSICAL FUNCTION OVER 52 WEEKS IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS

Mughal F¹, Tencer T², Clancy Z², Zhang F²¹Celgene Corporation, Uxbridge, UK, ²Celgene Corporation, Warren, NJ, USA

OBJECTIVES: The PALACE studies compared the efficacy and safety of apremilast (APR) with placebo in patients with active psoriatic arthritis (PsA) despite prior conventional disease-modifying antirheumatic drugs and/or biologics. The objective was to assess the impact of APR on physical functioning in patients enrolled in the PALACE trials. **METHODS:** The pooled analysis included data from PALACE 1-3, three 52-week, randomized, placebo-controlled studies evaluating APR in subjects with active PsA. Patients were randomized (1: 1) to placebo, APR 20 mg BID (APR20), or APR 30 mg BID (APR30). Patients with <20% reduction from baseline in swollen and tender joint counts at Week 16 were required to be re-randomized (1: 1) to APR20 or APR30 if initially randomized to placebo, or continued their initial APR dose. At Week 24, all remaining placebo patients were re-randomized to APR20 or APR30. The analysis reports data from the APR-exposure period (Weeks 0 to 52). Physical function, a pre-specified secondary end point, was measured using the Health Assessment Questionnaire-Disability Index (HAQ-DI) and the 36-item Short-Form Health Survey version 2 Physical Functioning (PF) domain and physical component summary (PCS) scores. **RESULTS:** At Week 16, the observed physical function change from baseline was improved with APR20 and APR30 vs. placebo, as measured by the HAQ-DI (-0.17 [$p < 0.001$] and -0.23 [$p < 0.001$] vs. -0.07), PF (2.73 [$p < 0.007$] and 4.08 [$p < 0.001$] vs. 1.52), and PCS (3.44 [$p < 0.002$] and 4.46 [$p < 0.001$] vs. 2.03). At Week 52, among patients who were treated with APR continuously, the physical function change from baseline for APR20 and APR30 was improved, as measured by the HAQ-DI (-0.30 and -0.33), PF (5.55 and 5.53), and PCS (6.37 and 6.23). **CONCLUSIONS:** Patients treated with APR30 reported improvement in physical function compared with placebo, as measured by the HAQ-DI, PF, and PCS. This response was maintained over 52 weeks.

PMS2

WORK PRODUCTIVITY IMPROVEMENT ASSOCIATED WITH APREMILAST, AN ORAL PHOSPHODIESTERASE 4 INHIBITOR, IN PATIENTS WITH PSORIATIC ARTHRITIS RESULTS OF A PHASE 3, RANDOMIZED, CONTROLLED TRIAL

Zhang F¹, Tencer T¹, Li S¹, Strand V²¹Celgene Corporation, Warren, NJ, USA, ²Biopharmaceutical Consultant, Portola Valley, CA, USA